COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 26.10.2009
SEC(2009) 1405 final

COMMISSION STAFF WORKING DOCUMENT

Executive Summary of Impact Assessment

Accompanying document to the

COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT, THE COUNCIL, THE EUROPEAN ECONOMIC AND SOCIAL COMMITTEE AND THE COMMITTEE OF THE REGIONS

Combating HIV/AIDS in the European Union and neighbouring countries, 2009 -2013

{COM(2009) 569 final}
{SEC(2009) 1403}
{SEC(2009) 1404}

1. PROBLEM DEFINITION

In view of the latest findings on HIV/AIDS, preliminary assessment of the 2006-2009 Action Plan, and stakeholder consultations, these are the issues for future action:

1.1. Political commitments have not been achieved

Despite some progress, certain agreed political commitments have not yet been met. The international community still supports agreed targets and realisable goals (universal access to prevention, treatment, care and support), but civil society is not systematically involved in policy development, implementation and monitoring in all Member States and neighbouring countries.

1.2. Data gaps in the centralised EU monitoring and reporting system

The ECDC has made progress in surveillance work on HIV/AIDS. But to obtain a complete picture of the epidemic, surveillance requires even more complete, comparable and compatible data.

1.3. Imperfect prevention and treatment activities and potentially diminishing health budgets

Prevention strategies are still not sufficiently effective. There are still large numbers of people living with HIV/AIDS (PLWHA) in Europe who have not yet been diagnosed. Counselling and voluntary testing are important instruments of HIV prevention, but they are not yet available throughout Europe. The same applies to access to treatment, care and support. Policies have to be targeted towards the particularly affected groups (e.g. injecting drug users (IDU), men having sex with men (MSM), and immigrants from high-prevalence regions).

The disease has changed from a deadly threat to a chronic condition, and support still varies across Europe and neighbourhood, and is far from universal[1]. Persisting knowledge gaps

Knowledge gaps persist in:

(i) Social science and especially the behavioural aspects of HIV transmission,
(ii) Socio-economic analysis on the cost-effectiveness of prevention,
(iii) The development and use of novel prevention technologies,
(iv) The cross-border dimension in the EU and neighbouring countries,
(v) Intensified biomedical research on treatments and vaccines.

1.4. Worrying trends in several Eastern European countries

Eastern Europe (Baltic Member States, Ukraine, Republic of Moldova; and the Russian Federation) is one of the regions of the world with an alarming spread of HIV, often with co-infections such as (multi-drug resistant) tuberculosis or hepatitis.

2. THE RATIONALE FOR EUROPEAN ACTION

Addressing the HIV/AIDS challenge at EU level is part of overall health and social policy, focusing on prevention and new strategies aimed at PLWHA and populations at risk, to reduce the spread of infections into the EU.

[1] Costs for antiretroviral HIV treatment and treatment of AIDS-related symptoms can be significant, and ARV costs are only a fraction of total treatment and follow-up costs for people with progressive disease.

2.1. Subsidiarity

EU Member States and neighbouring countries have the prime responsibility for protecting and improving the health of their citizens. Article 152 EC requires a high level of human health protection in the definition and implementation of all Community policy and activities.

2.2. Necessity test

HIV/AIDS is a communicable disease that needs to be addressed by coordinating the efforts of national governments. Cross-border movements affect the spread of HIV, but free movement of persons is a key political pillar of the EU.

An estimated 64 million migrants from non-EU countries currently live in the EU. Although they come from a large variety of countries, immigrants to the EU have a relevant share of new heterosexually transmitted HIV infections. This group is also at risk of social exclusion, so may have limited access to testing, prevention, treatment, care and support.

The EU needs a harmonised surveillance system to track epidemiological trends and assist Member States in taking adequate public health measures. It needs a common research agenda, to exploiting economies of scale. It is in the EU's interest to involve the neighbouring countries given the high prevalence of HIV/AIDS in some of these countries.

2.3. EU added value

The Commission should continue to play an important role in coordinating efforts across Europe to address HIV/AIDS. HIV infections are preventable. The Commission provides a solid fund of knowledge, a forum for discussion and exchanges between Member States to promote the transfer of ideas and approaches. Single Member States can hardly maintain this kind of cross-border cooperation.

The EU could mainstream HIV as a public health challenge across relevant EU policies, especially free movement of people, human rights, research and non-discrimination. Countries may benefit if they attune their own policies to European good practice.

3. POLICY OBJECTIVES

The general objective is to contribute to the prevention and reduction of human illness and diseases stemming from HIV infections, to obviate sources of danger to human health, as laid down in Article 152 of the Treaty and to improve the quality of life of PLWHA and most at risk of infection.

3.1. Specific objectives:

(a) To maintain political leadership and stakeholders commitment and involvement

(b) To improve HIV/AIDS epidemiological data by monitoring

(c) To support EU Member States and neighbourhood countries, in developing public health interventions to:

- focus national strategies on populations most at risk,
- improve living conditions of vulnerable people at high risk of HIV, and ensure universal access to prevention, treatment, care and support
- adapt national strategies to address unmet challenges (under-diagnosis, new prevention methods, new treatment options etc.)

– despite the current economic crisis, ensure that sufficient funding is allocated to HIV/AIDS

(d) To address knowledge gaps in treatment, vaccine and microbicide development, public health research, behavioural science, socio-economic analysis.

4. POLICY OPTIONS

To attain the above objectives, three different options were compared.

4.1. Option 1: Baseline — continued implementation of current action plan, and evaluation

The initial 'baseline option' would extend the lifespan of the current action plan and continue the implementation of open actions. This would maintain the political backing of the EU, allowing the Commission and stakeholders to complete activities still in progress and to continue with successful activities. Indicators could be introduced to monitor results, for a comprehensive evaluation of the current action plan. Surveillance and research would continue, based on existing priorities and instruments.

4.2. Option 2: No EU policy or action plan on HIV/AIDS

The Commission would not opt for a new policy initiative on HIV/AIDS. The Commission would focus on existing funding activities/programmes, such as the Research Programmes, the Health Programme, European Social Fund, European Neighbourhood Policy Instruments (ENPI), external HIV policies, and on technical support through specialised agencies such as ECDC or EMCDDA. But without a new EU action plan on HIV/AIDS, HIV-related spending could be re-allocated. Surveillance by ECDC would continue without alignment to new, agreed policy needs.

4.3. Option 3: Current plus — a new Commission policy and action plan

The Commission would provide renewed political impetus to keep HIV/AIDS on political agendas. It would set out the main policy priorities for the fight against HIV/AIDS across Europe. A new Commission policy could provide the broad action lines and the Commission services and stakeholders, meeting in the Think Tank and the Civil Society Forum, could refine an operational action plan, with indicators to measure progress. This option would respond to the new trends and challenges identified (prevention, priority regions, priority groups). EU and stakeholder activities would build on the first EU action plan 2006-2009 and adjust the emphasis to relevant areas such as prevention, treatment and research.

4.4. Option 4: Discarded options

Legislation: HIV/AIDS is a health and social problem with a considerable political dimension, but there is no basis in the Treaty for a HIV-specific directive or regulation. Member States and neighbouring countries design their national plans and programmes; but national approaches benefit greatly from sharing best practices, experiences and evidence-based solutions.

Campaign: A European campaign on HIV could not take account of all situations and cultural sensitivities throughout Europe. It would not work for all populations at risk, and would therefore not be cost-effective or efficient.

5. ANALYSIS OF IMPACT

5.1. Option 1: Baseline option — continued implementation of current action plan

Economic impact

The **direct costs for the EU** would probably be similar to the previous period (2006-2009). The **evaluation** included in this option would gauge the impact of EU and national efforts on the epidemic.

This option would demonstrate continuity and would encourage continued high investment by **multiple stakeholders**.

Spending for activities financed through national budgets would probably remain stable compared to 2006-2009. None of the activities in the action plan would be binding on any party.

An agreed action plan, backed up by strong political commitment, effective sharing of best practices, and a solid fund of knowledge, would reduce inefficiencies and duplication of efforts and could support planning at national level.

However, in an **economic downturn**, national spending on health is expected to be cut back, especially in the short and medium term. There is a risk that HIV/AIDS-related expenditure could follow this trend. No additional MS costs are expected for reporting, as the ECDC surveillance is financed from the EU budget.

Social impact

This option should improve access to prevention, treatment and care and, in turn, have a positive social impact. Indeed, effective prevention programmes help to **reduce further transmission of HIV**. Prevention, earlier diagnosis and treatment can halt or **delay the progression of the disease and keep sufferers in work**, which may improve the **quality of life of PLWHA**.

ECDC surveillance would not meet new challenges and data needs without a new EU policy.

5.2. Option 2: No EU policy or action plan on HIV/AIDS

Economic impact

The **direct costs for the EU** would probably fall, but not greatly. Political and financial support might be less effective, due to a lack of political guidance in setting priorities. Absence of political motivation for EU cooperation on HIV/AIDS could affect the programmes' annual priorities and favour other non-HIV/AIDS priorities which are supported by an EU policy. With 2.7 million new HIV infections annually worldwide, and the need for a vaccination or cure, this appears difficult to justify.

Reduced emphasis on HIV/AIDS as a priority would also have serious repercussions on **multiple stakeholders** engaged in research, service provision, training and support activities. In an economic crisis, the lack of political commitment at EU level would **not** necessarily be **compensated** by bilateral or multilateral cooperation without EU participation.

The key drawback is the political message that this would send. HIV/AIDS **prevention** programmes are particularly vulnerable to health budget cuts. Less prevention could make **health costs** increase, with more infections and higher treatment costs, as well as social, economic and labour market effects. No additional costs for MS for **reporting and surveillance** are to be expected.

Social impact

This option bears the risk that without political support from the Commission, HIV/AIDS might disappear from the radar screens of certain funding mechanisms.

It is difficult to tell what additional action would be taken by MS and stakeholders without EU political guidance. It may be assumed that **internationally agreed targets** would not be reached in all European countries. That could lead to adverse social impacts and an increase in HIV/AIDS.

There would be less potential to **empower NGOs** that protect vulnerable groups in the EU and neighbouring countries.

This option may not be effective enough to sustain cooperation across Europe, specifically to steer action towards the **new challenges**, or to address the **social issues**. As in the case of Option 1, **ECDC surveillance** would not cover the new challenges and data needs.

5.3. Option 3: Current plus — a new EU policy and action plan

Economic impact

Under this option, the tasks for implementing the new action plan would be distributed among all stakeholders involved.

The **direct costs for the EU** would probably be similar to the previous period (2006-2009). With political support and an increased focus on new challenges and trends, the effects could improve and resources could be reallocated towards more efficient action. The planned **evaluation** would help to gauge the impact of EU and national efforts on the epidemic. This option maintains HIV/AIDS as a priority at the EU level, emphasising continuity and providing an incentive for **multiple stakeholders** engaged in research, services, training etc.

Under this option, **spending for activities financed through national budgets** would probably remain stable, as compared to 2006-2009. None of the activities would be binding on any party. However, the emphasis on new priorities could lead to **reallocation of national resources** to new preventive methods, more targeting at the most-at-risk groups and stronger eastern cross-border cooperation, resulting in more cost-effective action.

The **economic downturn** could affect HIV/AIDS-related aid and threaten **prevention** programmes with potential health budgets cuts. Option 3 would give an incentive for EU MSs and neighbouring countries to maintain public spending targeted at most-at-risk populations and allocate resources to the most cost-effective health interventions.

Improved **reporting and surveillance** may impose additional costs on the very few countries not already sending sufficient data to ECDC. For other countries, there would be no additional burden. They will benefit from better planning based on better data — this is usually cost-effective.

Social impact

A Commission communication and action plan would underline **continuity** and **political will** to achieve existing **international commitments**. It would lay down precise targets and could result in **better resource allocation and more effective infrastructures** at a national level.

Option 3 should have a **positive impact** on **civil society**, **people affected by HIV/AIDS** and **industry.** Through stronger political leadership and civil society involvement, it should improve living conditions for all people affected by the disease.

This option would:

– support efforts to address the **social issues** around HIV/AIDS, related to stigma, discrimination, and non-respect of human rights

– empower civil society, which is indispensable in fighting HIV/AIDS

– monitor the scale of the epidemic and co-infections, such as tuberculosis, hepatitis and sexually transmitted infections, at national and cross-border level

– improve the response to it

– bring together experts to plan responses to future challenges.

Improved surveillance and monitoring at European level, mostly by ECDC and other specialised and norm-setting bodies, would strengthen the basis for effective and sustainable public health measures.

The following table summarises the impact of the three options on the specific objectives.

Specific objectives	**Option 1**	**Option 2**	**Option 3**
Political leadership and guidance towards agreed targets	+	-	++
Strengthened surveillance and epidemiology to support policy	+	+	++
Increase MS and neighbouring countries' focus on most-at-risk	+	-	++
Encourage MSs and neighbouring countries to improve living conditions for people at high risk of HIV and ensure universal access to high-quality care and treatment services	+	-	++
Encourage MSs and neighbouring countries to adapt HIV/AIDS strategies to non-resolved and/or new challenges	+	-	++
Encourage MSs and neighbouring countries to protect public and private anti-HIV/AIDS funding despite economic crisis	+	-	++
Fill research gaps by integrating resources and activities	+	+	++
Costs of specific objectives	*All figures are **approximate estimates***		
Budgetary impact for the EU:			
Health Programme	€20M	€20M or less, reallocation of HIV funding to other HP policies	€20M reallocation to new action plan priorities
Research Framework Programme	€100M	€100M or less, reallocation of HIV funding	€100M reallocation to new priorities
ECDC (surveillance and monitoring)	€4.4M	€4.4M	€4.4M reallocation to new priorities
Budgetary impact for MSs:			
Costs for health and research budgets	n/a stable	n/a risk of budget cuts, due to economic crisis	n/a stable reallocation to new priorities
Costs of reporting (surveillance)	no additional administrative burden for EU MSs	no additional administrative burden for EU MSs	administrative costs due to new data reporting requirements

Based on the impact assessment carried out, Option 3, a new Commission policy and action plan, would have the biggest impact, and thus is the preferred option.

6. MONITORING AND EVALUATION

Achievements could be tracked and monitoring reports could be published by the Commission by 2012. Regular monitoring encourages all stakeholders to share their results and achievements promptly. Best practices and opportunities for cooperation would be more accessible to all parties.